Remarks:

This Amendment is responsive to the Office action dated July 5, 2006. Prior to entry of this Amendment, claims 1-10 and 29-33 were pending in the application with claim 34 having been withdrawn by the Examiner. The Examiner provisionally rejected claims 1, 4, 6-8, and 29 under the non-statutory obviousness-type double patenting doctrine over claims 1-4, 8, 12-13, 15-16, 32-34, 37-40, 42-43, and 46 of copending Application No. 10/801,380. Further, claims 1, 4-6, and 29 are provisionally rejected under the non-statutory obviousness-type double patenting doctrine over claims 1, 3, 4, 6, 36, and 29 of copending Application No. 10/801,379.

Claims 1-3, 6-8, 29-30 and 32-33 stand rejected under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 4,322,449 to Voss et al. ("Voss et al.) or in the alternative as obvious over it under 35 U.S.C. § 103(a). Claims 9-10 and 31 stand rejected under 35 U.S.C. § 103(a) based on Voss et al. Claims 4-5 stand rejected under 35 U.S.C. § 103(a) based on Voss et al. in view of U.S. Patent No. 5,894,841 to Voges ("Voges"). Applicants respectfully traverse the rejections.

Double Patenting Rejections

As suggested by the Examiner, Applicants have filed terminal disclaimers to address each provisional, non-statutory, double patenting rejection rendered for this Application. Accordingly, Applicants submit that claims 1, 4, 6-8, and 29 provisionally rejected over claims 1-4, 8, 12-13, 15-16, 32-34, 37-40, 42-43, and 46 of copending Application No. 10/801,380 and claims 1, 4-6, and 29 provisionally rejected over

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claims 1, 3, 4, 6, 36, and 29 of copending Application No. 10/801,381 are now in condition for allowance.

Restriction Requirement

Applicants respectfully traverse the requirement to restrict claim 34 from the current application for the following reasons.

The amendments made to claim 34 in the June 12, 2006 Amendment did not change its scope. Prior to the June 12, 2006 Amendment, claim 34 recited selecting a second drop location "to achieve a desired surface-to-mass ratio." Following the Amendment, claim 34 recites an additional element "identifying a desired surface-to-mass ratio." As such, the Amendment merely clarified claim 34 by providing more clear antecedent basis for the existing claim elements without altering the claim scope. No requirement to restrict claim 34 was issued prior to the June 12, 2006 Amendment. Accordingly, Applicants submit that the requirement to restrict claim 34 when it continues to be directed to the same scope it was always directed to is improper.

Consistent with claims 1-10 and 29-33, claim 34 achieves a desired dissolution rate by positioning drops of solution at selected locations on the delivery substrate. Similarly to claims 1-10 and 29-33, claim 34 recites "a method of controlling a dissolution rate" and as such is not an independent or distinct invention from the prior claims. The achievement of a desired surface-to-mass ratio is an intermediate attribute of positioning drops of solution at selected locations to control a dissolution rate of a bioactive agent. Accordingly, claim 34 recites subject matter that is not independent or distinct from the other pending claims in the Application.

Thus, Applicants respectfully traverse the requirement to restrict claim 34 from the Application and request examination of it on its merits.

Rejections under 35 U.S.C. 102(b) or in the alternative under 35 U.S.C. 103(a)

Claims 1-3, 6-8, 29-30 and 32-33 stand rejected under 35 U.S.C. § 102(b), or in the alternative under 35 U.S.C. 103(a), based on to Voss et al. Voss et al. discloses a method for using a piezoelectric dosing system to dot a liquid active substance onto a substrate. The piezoelectric dosing system is shown below:

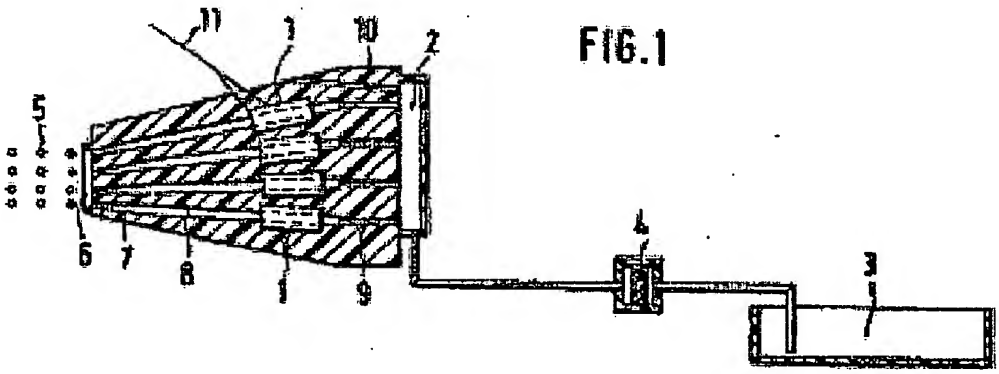

FIG.1

Voss et al. discusses controlling dosing at column 4, lines 13-26 as follows:

> The dosing may be controlled by one or more of the following parameters:
> (a) the diameter of the outlet opening of the nozzle channels;
> (b) the voltage applied to the piezoelectric oscillator;
> (c) the droplet frequency;
> (d) the number of nozzle channels;
> (e) the stroke intensity of the tubular or planar oscillator used;
> (f) the active substance concentration of the solution or suspension; and
> (g) the number of dots of active substance per pharmaceutical carrier.

While Voss et al. al. discloses a number of means for controlling dosing, it does not address each feature recited in the claims.

Claims 1-3 and 6-8

Voss et al. does not disclose or suggest each feature recited in independent claim 1. Claim 1 recites:

> A method of controlling a dissolution rate of a bioactive agent, the method comprising:
> identifying a target dissolution rate;
> applying a first drop of solution carrying the bioactive agent at a first selected location on a delivery substrate; and
> positioning a second drop of solution carrying the bioactive agent at a second selected location on the delivery substrate, wherein the location of the first drop and the location of the second drop are selected based on the target dissolution rate.

Features recited in claim 1 such as identifying a target dissolution rate and positioning first and second drops at locations selected based on the target dissolution rate are not disclosed or suggested in Voss et al.

The Examiner acknowledges that Voss et al. does not disclose or suggest identifying a target dissolution rate. However, she takes the position that it would have been inherent to identify a target dissolution rate when selecting a target dose. Applicants respectfully disagree with this position. The Examiner equates a *target* dissolution rate with an *acceptable* dissolution rate, i.e. a rate that is not too rapid and not too slow. However, a target dissolution rate is more specific than an acceptable dissolution rate. There is typically a range of dissolution rates that provide acceptable dosing, but one may desire to target one specific dissolution rate to achieve a variety of objectives. Claim 1 recites selecting a target dissolution rate, **not** selecting a target dose and ensuring that its dissolution rate is acceptable.

Moreover, Voss et al. does not disclose or suggest means for achieving a target dissolution rate. Claim 1 recites positioning drops at locations based on the target dissolution rate. Voss et al. pertains to dotting solutions of known concentrations such that "extremely accurate dosing is made possible." (Col. 5, ln. 64). Dosing is different than the dissolution rate of a bioactive agent. Dosing refers to the quantity of bioactive agent delivered and dissolution rate refers to the speed in which the bioactive agent dissolves. Instead of means for achieving a target dissolution rate, Voss et al. discloses means for achieving a target dose. For example, in Example 2 of Voss et al. the concentration of each drop was adjusted so that 250 drops would provide a total dose of 0.1 mg of active substance. Means to achieve a desired dose, or quantity of active substance, is not the same as means to achieve a desired dissolution rate. Thus, Voss et al. does not disclose or suggest means to achieve a target dissolution rate.

Voss et al. does not disclose or suggest a method including positioning dots at selected locations based on the target dissolution rate. Indeed, Voss et al. discloses dotting a substrate such that a geometric pattern arises for the purpose of visually coding or labeling the substrate. Further, it provides that more or fewer dots may be applied to a substrate to achieve more exact dosing and that uniform dotting of a substrate can be achieved due to the arrangement of micro-pumps in its dotting apparatus. Such disclosures, however, are not selecting locations to position dots based on a target dissolution rate. Except for the brief mention that the dotting apparatus could be configured to apply dots with uniform spacing, Applicants are not aware of any discussion relating to selecting the spacing of first and second drops of a

bioactive agent. Thus, Voss et al. does not disclose or suggest positioning dots at selected locations based on a target dissolution rate as recited in claim 1.

For at least the reasons discussed above, Voss et al. does not disclose or suggest each feature recited in claim 1. Accordingly, Voss et al. does not anticipate claim 1 under 35 U.S.C. § 102(b) or make a *prima facie* case that it is obvious under 35 U.S.C. § 103(a). It follows then that such rejections can not stand for claims 2, 3, and 6-8 depending from claim 1. Applicants, therefore, submit that the aforementioned claims are allowable.

Claims 29, 30, 32 and 33

Voss et al. does not disclose or suggest each feature recited in independent claim 29. Claim 29 recites:

> A method of controlling a dissolution rate of a bioactive agent, the method comprising:
> identifying a target dissolution rate;
> applying a first drop of solution carrying the bioactive agent at a first location on a delivery substrate;
> selecting a second location on the delivery substrate for placement of a second drop of solution carrying the bioactive agent from a plurality of possible second locations, the second location being selected in relation to the first location based on the identified target dissolution rate; and
> positioning the second drop of solution at the selected second location on the delivery substrate.

Identifying a target dissolution rate is not disclosed or suggested in Voss et al. Rather, Voss et al. identifies a target dose, or quantity, of active substance to apply to a substrate. Because the quantity of active substance applied to a substrate does not pertain to the dissolution rate of a bioactive agent, Voss et al. does not disclose identifying a target dissolution rate.

Voss et al. does not disclose or suggest selecting a second location in relation to a first location based on an identified target dissolution rate. What Voss et al. does disclose is applying dots such that they form letters or symbols, uniformly applying dots at whatever spacing results from the orientation of micro-pumps in a dotting system, and applying more or fewer dots to a substrate to increase or decrease the dose. While every time more than one drop of liquid is dotted onto a substrate there will be a given spacing between the drops, claim 29 recites selecting the location of one dot relative to another based on an identified target dissolution rate. This feature is not disclosed or suggested in Voss et al.

Accordingly, Voss et al. does not disclose or suggest each feature recited in claim 29. As such, the features recited in claims 30, 32, and 33 depending from claim 29 are not disclosed or suggested by Voss et al. Therefore, Applicants submit that claims 29, 30, 32 and 33 are allowable under 35 U.S.C. § 102(b) and 35 U.S.C. § 103(a).

Rejection under 35 U.S.C. § 103(a)

The Examiner has rejected claims 9, 10, and 31 as being unpatentable over Voss et al. However, Voss et al. does not disclose or suggest each feature recited in the claims from which claims 9, 10, and 31 depend as discussed above. Accordingly, the issue of whether the additional subject matter recited in claims 9, 10, and 31 is obvious over Voss et al. is obviated and will not be addressed for the sake of brevity. Applicant submit that because claim 1 and 29 are allowable over Voss et al., claims 9, 10, and 31 are likewise allowable under 35 U.S.C. § 103(a).

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Conclusion

Applicants believe that this application is now in condition for allowance, in view of the above amendments and remarks. Accordingly, Applicants respectfully request that the Examiner issue a Notice of Allowability covering the pending claims. If the Examiner has any questions, or if a telephone interview would in any way advance prosecution of the application, please contact the undersigned attorney of record.

Respectfully submitted,

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CERTIFICATE OF FACSIMILE TRANSMISSION

I hereby certify that this correspondence is being facsimile transmitted to Examiner J. Michener, Group Art Unit 1762, Assistant Commissioner for Patents, at facsimile number (571) 273-8300 on October 5, 2006.

Christie A. Doolittle